REMARKS/ARGUMENTS

After the foregoing Amendment, claims 1 – 14, 16, and 27 – 32 are currently pending in this application. Claims 15, and 17 – 26 were previously canceled without prejudice. Claims 1, 2, and 8 have been amended. Applicants submit that no new matter has been introduced into the application by these amendments.

Claim Rejections - 35 USC § 103

Claims 1 – 4, 11 – 14, and 28 – 31 were rejected in the Office Action under 35 USC § 103(a) as obvious over EP 0373294 (hereinafter "Shimada") in view of USPN 3,804,802 (hereinafter "Bergna").

Claims 5 – 10, 16, 27 and 32 were all rejected under 35 USC § 103(a) as obvious over Shimada in view of various combinations with:

Bergna;

WO 91/02906 ("Gapp");

USPN 5,074,772 ("Gutjahr");

WO 92/10542 (USPN 5,342,664, English language equivalent ("Drotloff"));

USPN 5,244,747 ("Lee"); and

USPN 4,356,230 ("Emmanuel").

Applicants respectfully traverse the rejection. The present invention as claimed in independent claim 1 is a process for manufacturing medical components made of fiber-reinforced thermoplastic materials. A blank formed of fibers and thermoplastic materials is first pre-finished, and the blank is brought into a final

form of a component in a negative mold, under pressure, in a hot-forming process. The process includes the steps of heating the entire blank to a forming temperature with plastic flow consistency in a heating stage located outside the negative mold. The process also includes pressing the heated blank into the negative mold using a pressing head that travels at a speed of 2mm/sec to 80 mm/sec, generally maintaining orientation of the fibers in the heated blank. Finally, the process includes shaping the blank in the negative mold by virtue of the entire blank flowing from the heating stage into and filling up the negative mold.

The present invention as currently claimed in independent claim 2 is a process for manufacturing medical components made of fiber-reinforced thermoplastic materials. A blank, formed with a fiber proportion of more than 50 volume-% and includes endless fibers and the fiber-reinforced thermoplastic material, is first pre-finished. The blank is brought into a final form of a component in a negative mold, under pressure, in a hot-forming process. The process includes heating the entire blank to a forming temperature with plastic flow consistency in a heating stage located outside the negative mold. The process also includes pressing the heated blank into the negative mold using a pressing head that travels at a speed of 2mm/sec to 80 mm/sec, generally maintaining orientation of the fibers arranged in the heated blank. Finally, the process includes shaping the blank in

the negative mold by virtue of the entire blank flowing from the heating stage into and filling up the negative mold.

Shimada discloses a process for the production of threaded fiber reinforced fasteners. Shimada deals with a process where thread rolling or die forging is used so that only a partial molding of a blank takes place. The blank is placed in the mold cavity, is warmed and die cast. The process also includes pressing a ram into the negative mold to press the fibers into the threaded portions of the mold, where a majority of the fibers are displaced, rearranged, or broken. Furthermore, this can only occur when the site of the warming of the blank is the negative mold itself, which is in total contrast to the claimed invention. The Examiner admits that Shimada does not teach two of the limitations of the independent claims, namely, (a) the heating stage located outside the negative mold, and (b) pressing the heating blank at a speed of 2 mm/sec to 80 mm/sec. The Examiner however, alleges that Shimada teaches heating prior to pressing into the negative mold (11: 40 – 12: 5). This is entirely inaccurate. Shimada states in 11:40 – 12: 5 (emphasis added): "The rod material 6 is cut off to have a prescribed length and inserted into the hole 84 of the second mold member 73 in such a manner that the longitudinal axis of the rod material 6 is generally aligned along with the axis of the hole 84. Then, a primary molding process begins. The material 6 is heated to soften. Next, a ram 90 is advanced and inserted into the hole 84 by a pressure device (not shown). The ram

90 has a rod-like presser 92 of a circular cross section and a flange 94 concentrically attached to the presser 92. The presser 92 is of a length and a diameter the same as that of the smooth portion 88. The presser 92 has a circular recess 96 at the forward end thereof, whose diameter is smaller than that of the material 6. The depth of the recess 96 is selected to suit the capacity of the mold 70, the volume of the material 6, and the desired pressing ratio of the material 6. Accordingly, the heated material 6 is axially pressed by the ram 90 as shown in Fig. 10. One end of the material 6 which is closer to the first mold member 72 spreads and broadens around the projection 78 and is injected into the second molding chamber under the guidance of the projection." As a result, the orientation of the fibers arranged in the heated material 6 is not generally maintained as is currently claimed. Figs. 9 and 10 of Shimada are reproduced below.

FIG. 9

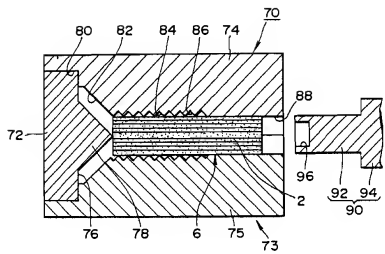
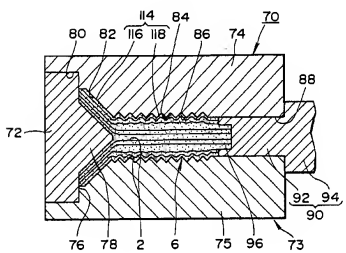


FIG. 10



The proposed combination fails to disclose all of the limitations of the claim since the entire blank is not heated to a forming temperature with plastic flow consistency in a heating stage **located outside the negative mold**, nor does the combination show or suggest pressing said heated blank into the negative mold using a pressing head that travels at a speed of 2mm/sec to 80 mm/sec**, generally maintaining orientation of the fibers in the heated blank,** as is currently claimed.

Furthermore, the combination of the axially-pressure formed screw reference, Shimada, with the high-pressure injection molding of thermoplastic composite with low alkali glass fillers reference, Bergna is inappropriate.

Shimada discloses processes for forming airplane screws (Col. 1, lines 8 - 16), which ignores the sterility and precision required in medical applications. JP 02-145327 describes a nylon resin and braided yarn reinforced screw that is formed in a mold and axially compressed by a punch.

Rejections over JP 02-145327

Claims 1 – 5, 11 – 14, and 28 – 31 were rejected under 35 USC § 103(a) as obvious over JP 02-145327 in view of USPN 4,356,228 (hereinafter "Kobayashi et al.") and further in view of USPN 5,156,588 (hereinafter "Marcune et al").

Claims 5 – 10, 16, 27 and 32 were all rejected under 35 USC § 103(a) as obvious over JP 02-145327 in view Kobayashi and further in various combinations with:

WO 91/02906 ("Gapp");

USPN 5,074,772 ("Gutjahr");

WO 92/10542 (USPN 5,342,664, English language equivalent ("Drotloff"));

USPN 5,244,747 ("Lee"); and

USPN 4,356,230 ("Emmanuel").

Applicants traverse the rejection. JP 02-145327 discloses method for manufacturing a fiber reinforced screw member by forming a solid or hollow bar shaped fiber reinforced molded plastic part with reinforcement fiber bundles at least on an outside surface or an near an inside surface. The molded part is placed in a mold and is compressed in an axial direction. The outer surface of a bulked reinforcement fiber bundle (bulked yarn) 10 is so covered in a tubular state with nylon resin. The resin-coated bulked yarns are knitted as a braided string 13. The strings 13 and resin-coated bulked yarns are so disposed that the strings 13 are aligned on the outer periphery, and extrusion molded to obtain a solid round rod 14. Then, the rod 14 is cut in a predetermined thickness. The cut piece is **inserted into a screw forming mold, heated together with the mold**, and axially compression deformed by a punch to obtain a screw member.

JP 02-145327 does not show or suggest any of the steps of the claimed process, namely heating the entire blank to a forming temperature with plastic flow consistency in a heating stage located **outside** the negative mold, pressing said heated blank into the negative mold using a pressing head that travels at a speed of 2mm/sec to 80 mm/sec, generally maintaining orientation of the fibers in the heated blank, and shaping the blank in the negative mold by virtue of the entire blank flowing from the heating stage into and filling up the negative mold.

Kobayashi, in contrast, discloses several processes for **extruding** composite **sheets** for use in "press molding, compression molding, stamping molding," although Kobayashi admits that "method of molding the preheated sheet is not particularly critical in the present invention." Col. 5, lines 3-4 and 12-13. The mere inclusion of the medical device patent (Marcune) does not somehow knit together the disparate screw, and sheet references into a proper combination.

Because there is no suggestion to combine the construction, sheet-forming and medical arts, especially as one of ordinary skill in the art would recognize the shortcomings of using a sheet-forming process in forming **precision medical screws**, which require biocompatibility. Sheet-forming, using an extrusion or press, would not be practical for use in forming a screw, with its fine threads and engagement surface, and thus would never be consulted to look up a suggested injection molding pressing head speed, as has been done in the Action.

The combination of these references is, at best, a tenuous weave of unrelated references; at worst, the references were cobbled together only after studying the pending claims, and using these claims as a blueprint for the rejections. In either case, the combination is improper.

Based on the amendments and arguments presented above, withdrawal of the 35 USC § 103(a) rejection of the claims is respectfully requested.

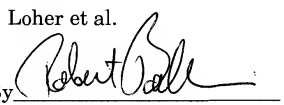
Conclusion

If the Examiner believes that any additional minor formal matters need to be addressed in order to place this application in condition for allowance, or that a telephone interview will help to materially advance the prosecution of this application, the Examiner is invited to contact the undersigned by telephone at the Examiner's convenience.

In view of the foregoing amendment and remarks, Applicants respectfully submit that the present application, including claims 1 – 14, 16 and 27 – 32, is in condition for allowance and a notice to that effect is respectfully requested.

Respectfully submitted,

Loher et al.

By 

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